

Texas State Board of Pharmacy
Laws and Rules Update
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Texas Pharmacy Law Update

April 6, 2016



Goals

- Review recent changes to pharmacy rules;
- Review the most common Warning Notices Issued to Pharmacies;
- Review pharmacy related legislation passed by the 2015 Legislature; and
- Review some current issues facing the Board.



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Recently Adopted Rules



Grounds for Discipline

- Effective Date: December 6, 2015.
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.



Grounds for Discipline

- Effective Date: Effective mid-March 2016.
- It is a ground for discipline of a pharmacy license if the owner, managing officer(s), or other pharmacy employee(s) exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member's or employee's lawful duties.



Pharmacist-in-Charge

- Effective Date: December 6, 2015.
- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
 - Class B Pharmacy; or
 - Class C Pharmacy in a hospital with 101 beds or more.



Administration of Immunizations and Vaccines

- Effective Date: December 6, 2015.
- Before preparing an immunization/vaccine **and** between each patient contact:
 - Pharmacist must:
 - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
 - wash their hands with soap and water.
 - If gloves are worn, pharmacists must change gloves between patients.



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Pharmacists and Pharmacy Technicians



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Pharmacist's Continuing Education

- Effective Date: March 17, 2013.
- Pharmacists can receive credit for programs approved by AMA as Category 1 CME.
- Pharmacists must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



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Pharmacy Technician's Continuing Education

- Effective Date: June 12, 2013.
- Pharmacy Technicians must report 1-hour of CE related to Texas Pharmacy Laws or Regulations on renewals received after 1/1/15.



Pharmacy Technician's Continuing Education (cont.)

- Effective Date: September 14, 2015.
Amendments to §297.8 (Continuing Education) rules to:
 - Decrease the number of in-service hours from 10 to 5 hours;
 - Clarify the requirements for CE; and
 - Clarify the types of programs that count for continuing education.



Licensing Fee Changes

| License | Renewal Fee Effective October 1, 2015 | Change |
|---------------------------------|--|---------------|
| Pharmacist | \$276 | \$25 decrease |
| Pharmacies | \$452 | \$80 decrease |
| Pharmacy Technicians | \$77 | \$19 decrease |
| Pharmacy Technician Trainees | \$52 | \$10 decrease |



Conditions Receiving "Warning Notices" FY2015



Number of Inspections

| Class | FY2015 | % of FY2015 Inspections |
|--------------------|--------|-------------------------|
| Class A Pharmacies | 2,275 | 76% |
| Class A-S | 144 | 5% |
| Class B Pharmacies | 5 | <1% |
| Class C Pharmacies | 268 | 9% |
| Class C-S | 128 | 4% |
| Class D Pharmacies | 95 | 3% |
| Class F Pharmacies | 61 | 2% |
| Class G Pharmacies | 15 | <1% |
| Totals | 2,991 | 100% |

Warning Notices

| Class | # Pharmacies Receiving WN | % Receiving WN |
|-----------|---------------------------|----------------|
| Class A | 992 | 77% |
| Class A-S | 84 | 6% |
| Class B | 2 | <1% |
| Class C | 80 | 6% |
| Class C-S | 87 | 7% |
| Class D | 31 | 2% |
| Class F | 17 | 1% |
| Class G | 0 | N/A |
| Totals | 1,293 | 100% |

**Most Common Warning Notices
(All Classes of Pharmacy)**

| Violation | Number of WN Issued* | % of Total WN |
|--|-------------------------|------------------|
| Records | 731 | 9% |
| Sterile Preparations | 647 | 29% |
| Pharmacy Technicians | 564 | |
| Drug/Stock Environment | 421 | 14% |
| Prescriptions | 335 | 9% |
| Inventory | 319 | 5% |
| * One pharmacy may receive multiple Warning Notice violations. | | |

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

| Condition | Number of WN Issued | Total |
|--------------------------------------|------------------------|-------|
| Records | | 731 |
| Records Not Available | 314 | |
| Absence of R.Ph. Record | 66 | |
| Rx Not Separated | 17 | |
| Rx Records Not Numerical Order | 25 | |
| Improper Transfer of RX copies | 3 | |
| Invoices Not Separated/Retrievable | 122 | |
| Records for Non-Sterile Compounds | 169 | |
| No Written Information on RX | 10 | |

**Most Common Warning Notices
(All Classes of Pharmacy) cont.**

| Condition | Number of WN Issued | Total |
|--------------------------------|------------------------|-------|
| Sterile Preparations | | 647 |
| No/Incomplete QA/QC | 99 | |
| No/Incomplete P&P Manual | 237 | |
| No/Inadequate Preparation Area | 165 | |
| IV Preparation | 131 | |
| No DUR | 13 | |
| Cytotoxic/Bio Procedures | 2 | |

Most Common Warning Notices
(All Classes of Pharmacy) cont.

| Condition | Number of WN Issued | Total |
|-------------------------|------------------------|-------|
| Pharmacy Technicians | | 564 |
| No/Incomplete Training | 510 | |
| No/Improper Supervision | 19 | |
| Improper Registration | 29 | |
| No Name Tags | 6 | |

Most Common Warning Notices
(All Classes of Pharmacy) cont.

| Condition | Number of WN Issued | Total |
|----------------------------------|------------------------|-------|
| Drug Stock/Environment | | 421 |
| Improper Environment | 137 | |
| Out-of-Date Drug Stock | 158 | |
| Security | 65 | |
| Unsanitary | 32 | |
| Improper Drug Storage | 20 | |
| Area for Non-Sterile Compounding | 7 | |
| Violation of Limited Formulary | 2 | |

Most Common Warning Notices
(All Classes of Pharmacy) cont.

| Condition | Number of WN Issued | Total |
|------------------------------|------------------------|-------|
| Prescriptions | | 335 |
| Lack Proper Information | 159 | |
| Prescription Label Incorrect | 136 | |
| Official Rx Non-Compliance | 40 | |

Most Common Warning Notices (All Classes of Pharmacy) cont.

| Condition | Number of WN Issued | Total |
|----------------------------------|------------------------|------------|
| Inventory | | 319 |
| No Annual Inventory | 84 | |
| No Change of Ownership Inventory | 5 | |
| No Change of PIC Inventory | 35 | |
| Incomplete Inventory | 194 | |
| Improper Drug Destruction | 1 | |

Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



Violations NOT Resulting in Warning Notices

🔹 Egregious Conditions

- Dispensing CII's pursuant to prescriptions not issued on an Official Form;
- Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
- Pharmacy closed and did not notify TSBP of closing;
- Operating without a PIC for an extended period of time (i.e., 3 months or more).



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Violations NOT Resulting in Warning Notices

🔹 Continuing threat – For example:

- Impaired pharmacist on duty; or
- Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to “*cease and desist*” sterile compounding until conditions have been corrected.

- 🔹 Both of these scenarios would result in an Emergency Temporary Suspension Hearing.



TEXAS STATE BOARD OF PHARMACY

Pharmacy Related Legislation Passed by the 2015 Legislature



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S.B. 195 by Sen. Schwertner

- This bill:
- Moves the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminates the Texas Controlled Substance Registration program.



S.B. 195 by Sen. Schwertner

- Effective Date: 6/20/2015 for some provisions and 9/1/2016 for others.
- This bill:
 - Allows the Board, on or after 6/20/2015 to:
 - Adopt rules to implement the PMP and certain other provisions related to prescriptions in the Controlled Substances Act.
 - Sign a contract with a vendor to operate the PMP.



S.B. 195 by Sen. Schwertner

- February 2016 – Board adopted new Chapter 315 to implement PMP and provisions related to prescriptions in the Controlled Substances Act.



S.B. 195 by Sen. Schwertner (cont.)

- On 9/1/2016:
 - The Board will establish a program to fund the Prescription Monitoring Program (PMP) though a surcharge on the license fees of persons authorized to access the PMP.
 - **The PMP is transferred from the DPS to TSBP.**
 - The Controlled Substance Registration program is abolished.



Timeline for Transfer of the PMP Program

- **November 2015** – RFP for the new PMP issued by TSBP.
- **January 2016** – **Appriss selected as the vendor.**
- **February – May 2016** – System installation at TSBP.
- **May/June 2016** – Testing of program.
- **September 1, 2016** – NEW PMP goes live.



S.B. 460 by Sen. Schwertner

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint.
 - Require a pharmacy to file an application to change location at least 30-days prior to the move.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act to:
 - Eliminate the Generic Substitution Sign and modify the requirement for the Complaint Notification to allow electronic posting.
 - Specify that a pharmacy license may not be renewed if it has expired for 91 days or more.



S.B. 460 by Sen. Schwertner (cont.)

- Amends the Pharmacy Act for Class E Pharmacies to:
 - Allow the Board to discipline the pharmacy if it has been disciplined in their state.
 - Prohibit a person from owning the pharmacy if their R.Ph. license was revoked, suspended, restricted, surrendered in another state.
 - Require the pharmacy to have a Texas licensed pharmacist serve as the PIC for the Texas license.



H.B. 751 by Rep. Zerwas

- Effective Date: 9/1/2015.
- The bill allows the substitution of interchangeable biological products.
- Interchangeable biological products are those rated equivalent by FDA (Orange Book and the Purple Book).



H.B. 751 by Rep. Zerwas (cont.)

- The bill specifies that not later than the 3rd business day after dispensing the pharmacist must “*communicate*” to the prescribing doctor the name of the product provided and the manufacturer or NDC number.
- The bill outlines several methods to notify the prescriber.



H.B. 751 by Rep. Zerwas (cont.)

- Notification is not required if:
 - There is no interchangeable biological product approved by FDA; or
 - A refill prescription is not changed from the product dispensed on the prior dispensing.
- The notification section of the bill expires on 9/1/2019.



H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a pharmacist to administer epinephrine, using an auto-injector, to a patient in an emergency situation.
 - Specify a pharmacist may not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.



H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
 - Specify that a pharmacist who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.



Current Issues



Sunset Review

- Texas Pharmacy Act, Sec. 551.005.
Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.



Sunset Review Time Line

- August 2015.
 - TSBP prepares a Self-Evaluation Report.
- October 2015 – March 2016.
 - Sunset staff reviews the agency.
- Late March 2016.
 - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response.



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Sunset Review Time Line (cont.)

- April 2016.
 - Sunset staff report published.
- May 2016.
 - Sunset Commission holds a public hearing to receive public comment on the agency.
- Summer 2016.
 - Commission decisions are issued.
- January – May 2017.
 - 2017 Legislative Session

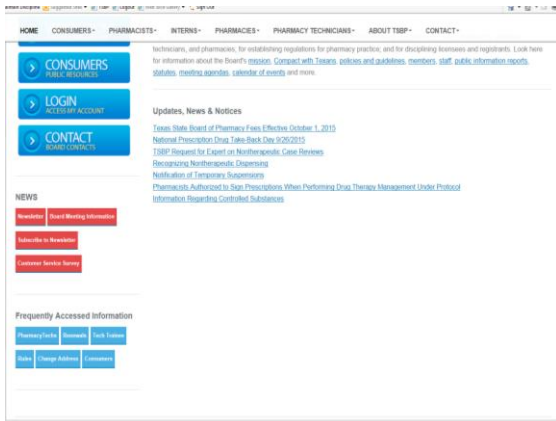


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TSBP Website
www.pharmacy.texas.gov



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Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the
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For questions about today's presentation, please email us at:

educationcoordinator@pharmacy.texas.gov